clinical rational for lumbar fusion surgery. Patients who underwent a ALIF, PLF or T/PLIF with "stand-alone" DDD had significantly lower total payments and significantly shorter LOS, while patients with DDD and additional back diagnoses had significantly higher total payments and longer LOS compared to patients who underwent an ALIF, PLF, or T/PLIF without a comorbid diagnosis of DDD.

PSU32

A COMPARISON OF RESOURCE UTILIZATION AND MEDICAL CHARGES AMONG LUMBAR INTERBODY FUSION SURGICAL PATIENTS WITH AND WITHOUT REVISION

Kemner JE[1], Lage MJ[2], Treglia M[2]
[1]Medtronic Spinal & Biologics, Memphis, TN, USA, [2]HealthMetrics Outcomes Research, Delray Beach, FL, USA

OBJECTIVES: Compare resource utilization and medical charges among patients who had an anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLF), or transforaminal posterior lumbar interbody fusion (T-PLIF) and a subsequent revision surgery to those without such a revision surgery. **METHODS:** The MedStat MarketScan databases from 2006 - 2009 were utilized for this retrospective analysis. Patients were included if had a ALIF, PLF, or T-PLIF and had continuous insurance coverage for 2 years post procedure. Revision patients were then matched to non-revision patients at a 2:1 ratio based upon type of initial procedure, year of birth, sex, and region of residence Medical payments and resource utilization were compared between the two cohorts using t-statistics for continuous variable and chi-square statistics for categorical variables. **RESULTS:** In the 2 years post procedure, patients with a subsequent revision were significantly more likely to visit a physical therapist (92% v 62%; P<0.0001), receive an epidural steroid injection (58% v 47%; P=0.0074), or visit the emergency room with a diagnosis of back pain (20% v 9%; P<0.0001). The average cost the initial surgery was similar among the two cohorts ($39,925 v $38,341; P=0.6422) while the mean cost associated with a revision surgery was $35,296 (std dev=$32,814). Total payments for the two cohorts, ignoring the cost of the initial procedure was $33,180 for patients who did not have a subsequent revision, and $89,770 for patients with a subsequent revision (P<0.0001). These differences translate into a $56,590 cost premium associated with a revision surgery – 62% of which can be accounted by the revision surgery itself. **CONCLUSIONS:** Revision surgery was associated with significantly more resource utilization post initial surgery. Comparing costs among the two groups reveal a significant cost premium associated with revision surgery and that such costs extended beyond the cost of the revision surgery itself.

PSU33

CHARACTERISTICS AND BURDEN OF TUBEROUS SCLEROSIS COMPLEX: RESULTS OF A PATIENT AND CAREGIVER SURVEY IN THE UNITED STATES

Pashos CL[1], Rentz A[2], Liu J[3], Pelletier C[4], Prestifilippo J[5], Nakagawa J[6], Frost MD[7], Dunn DW[8], Wheless JW[9]
[1]United BioSource Corporation, Lexington, MA, USA, [2]United BioSource Corporation, Bethesda, MD, USA, [3]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, [4]Novartis, Florham Park, NJ, USA, [5]Novartis, East Hanover, NJ, USA, [6]Tuberous Sclerosis Alliance, Silver Spring, MD, USA, [7]Minnesota Epilepsy Group, PA, St. paul, MN, USA, [8]Riley hospital for Children, Indianapolis, IN, USA, [9]Le Bonheur Children's Hospital, Memphis, TN, USA

OBJECTIVES: Tuberous sclerosis complex (TSC) is a rare genetic disorder characterized by benign tumor growth in multiple organs. TSC's subsequent and varied impacts on patients are typically treated by many different types of procedures. This study aimed to assess the principal clinical manifestations imposed by the disease and consequent major types of health care resource utilization experienced among TSC patients in the United States (US). **METHODS:** An Institutional Review Board-approved Internet-based survey of US TSC patients and caregivers solicited information on prevalence of manifestations, disease management, and impact on patients. Descriptive statistics were calculated. **RESULTS:** Of the 380 initial respondents, 53% were patients and 47% were caregivers. Surveys provided data on 380 patients, of whom 59% were female and the mean age was 30.4 years (SD: 17.3; median: 32.5). The majority of patients reported experiencing skin lesions (53%) while seizures, cognitive concerns, cerebral tumors, angiomyolipomas (AML), and subependymal giant cell astrocytomas (SEGA) were reported by 46%, 36%, 26%, 23%, and 21%, respectively. Ninety patients (24%) reported only one manifestation of TSC, while 18%, 14%, and 38% reported 2, 3, or 4 or more. Over half of patients (52%) had some type of TSC-related surgery including but not limited to brain surgery (33%), embolization (12%), nephrectomy (7%), kidney transplant (6%), and laser surgery (12%). Patients with SEGAs reported the highest level of brain surgery (55%). Among patients with AMLs, embolization for kidney lesions (28%), nephrectomy (12%) and kidney transplant (8%) were reported. **CONCLUSIONS:** In this analysis of initial respondents, TSC presents significant, and varied, epidemiological and clinical burden in the US. Patients with SEGA and AMLs seemed to experience the highest rates of invasive procedures among all patients with TSC.

PSU34

EPIDEMIOLOGICAL MODELING OF PATIENT SURVIVAL AFTER LIVER TRANSPLANTATION IN GERMANY

Jugl S, Langsdorf V, Schüle S
Novartis Pharma GmbH, Nuremberg, Bavaria, Germany

OBJECTIVES: The number of performed heart transplantations per year are well published and can easily be accessed. Nevertheless, there are no exact figures on the prevalence and incidence of patient survival after heart transplantation in Germany, although these patients have high health care needs. Purpose of this study was to generate these missing figures for the past and present as well as taking an outlook into the future development until 2030. **METHODS:** Primarily based on statistics from the Federal Statistical Office and liver transplant quality reports of the German AQUA-Institute, relevant parameters and data were identified and used to develop an epidemiological model. Key drivers of the model are yearly patient survival rates as well as growth rates of performed liver transplantations. The model starts in 1987 and is able to predict the future development of the cumulative liver transplant patient population until the year 2030. To account for uncertainty, a 1.000 replication Monte-Carlo-Simulation with random samples within published ranges of the input parameters was run. **RESULTS:** According to our model currently (2012) about 7.773 (95% Confidence interval: 7.701 – 7.844) patients with prior liver transplantation live in Germany. Until 2030 the model estimates an increase of the population size to 17.490 (95% CI: 17.105 – 17.875) people. The number of performed liver transplantations is estimated at 3.068 (95% CI: 2.988 – 3.148) in 2030. **CONCLUSIONS:** With current assumptions the liver transplant patient population size will continuously grow. The growth of this population will primarily be limited by available organs for transplantation.

PSU35

EPIDEMIOLOGICAL MODELING OF PATIENT SURVIVAL AFTER HEART TRANSPLANTATION IN GERMANY

Jugl S, Langsdorf V, Schüle S
Novartis Pharma GmbH, Nuremberg, Bavaria, Germany

OBJECTIVES: The number of performed heart transplantations per year are well published and can easily be accessed. Nevertheless, there are no exact figures on the prevalence and incidence of patient survival after heart transplantation in Germany, although these patients have high health care needs. Purpose of this study was to generate these missing figures for the past and present as well as taking an outlook into the future development until 2030. **METHODS:** Primarily based on statistics from the Federal Statistical Office and heart transplant quality reports of the German AQUA-Institute relevant parameters and data were identified and used to develop an epidemiological model. Key drivers of the model are yearly patient survival rates as well as growth rates of performed heart transplantations. The model starts in 1980 and is able to predict the future development of the cumulative heart transplant patient population until the year 2030. To account for uncertainty, a 1.000 replication Monte-Carlo-Simulation with random samples within published ranges of the input parameters was run. **RESULTS:** According to our model currently (2012) about 4.072 (95% Confidence interval: 4.028 – 4.116) patients with prior heart transplantation live in Germany. Until 2030 the model estimates a decrease of the population to 3.028 (95% CI: 2.980 – 3.077) people. Peak number of patients after heart transplantation was estimated at 2007: 4.225 (95% CI: 4.192 – 4.257). The number of performed heart transplantations is estimated at 266 (95% CI: 261-271) in 2030. **CONCLUSIONS:** Even though the peak number of patients with heart transplants according to our model has occurred in the past, still a considerable heart transplant patient population is living at Germany and seeking health care services for their needs.

PSU36

EVIDENCE BASED MEDICINE: A CASE STUDY OF ITS APPLICATION TO INNOVATIVE SURGICAL PROCEDURES IN THE UK

Mauskopf J[1], Beach W[2], Mcintyre L[3], Bhattacharyya SK[4], Higgins L[5], Mordin M[6], Copley-merriman K[6]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Tuckahoe Orthopaedic Associates, Henrico, VA, USA, [3]Westchester Orthopaedic Associates, White Plains, NY, USA, [4]DePuy Mitek, Inc., Raynham, MA, USA, [5]Brigham and Women's Hospital; Harvard Medical School, Boston, MA, USA, [6]RTI Health Solutions, Ann Arbor, MI, USA

INTRODUCTION: Evidence based medicine (EBM) is frequently used as the basis for clinical guidelines and reimbursement recommendations. The hierarchy of evidence is: Level I - randomized controlled trials (RCTs); Level II - nonrandomized cohort studies; Level III - case control studies, Level IV - case series, and Level V - expert opinion. RCTs are generally required when developing clinical guidelines or reimbursement recommendations for drugs. **OBJECTIVES:** The purpose of this case review is to illustrate an application of EBM to an innovative surgical procedure and highlight how the recommendations for use changed with new evidence. **METHODS:** NICE guidelines for arthroscopic surgery for femoro-acetabular impingement were reviewed. This case study was selected because the treatment modality represents a new surgical technology in which guidelines for coverage recommendations, first promulgated in 2007, were later changed in 2011, illustrating the impact of additional evidence generation. **RESULTS:** In 2007, efficacy evidence considered by NICE were two case series, with 158 and 10 patients respectively. In 2011, efficacy evidence considered by NICE covered 1126 patients from 3 non-randomized controlled studies (none compared with natural history or non-arthroscopic surgical techniques), 5 case series (with 100 to 200 hips), and 1 case report. Twenty-two smaller case series were also identified. In 2011, four out of five specialist advisors viewed the procedure as established while one advisor considered the efficacy and safety still to be uncertain. In 2007, NICE concluded "current evidence . . . does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research" while in 2011 NICE concluded "current evidence. . ... is adequate in terms of symptom relief in the short and medium term." **CONCLUSIONS:** For innovative surgical procedures in the UK, non-randomized controlled studies and case series, supported by specialist recommendation, may be sufficient for a positive recommendation by NICE.

DISEASE-SPECIFIC STUDIES

CANCER - Clinical Outcomes Studies

PCN1

USE OF THE 5-HT3-RA ANTIEMETICS IN THE PREVENTION AND TREATMENT OF RADIATION INDUCED NAUSEA AND VOMITING

Knoth RL[1], Faria C[1], Chang E[2], Broder M[2]
[1]Eisai, Inc., Woodcliff Lake, NJ, USA, [2]Partnership for Health Analytic Research, Beverly Hills, CA, USA